

PCT

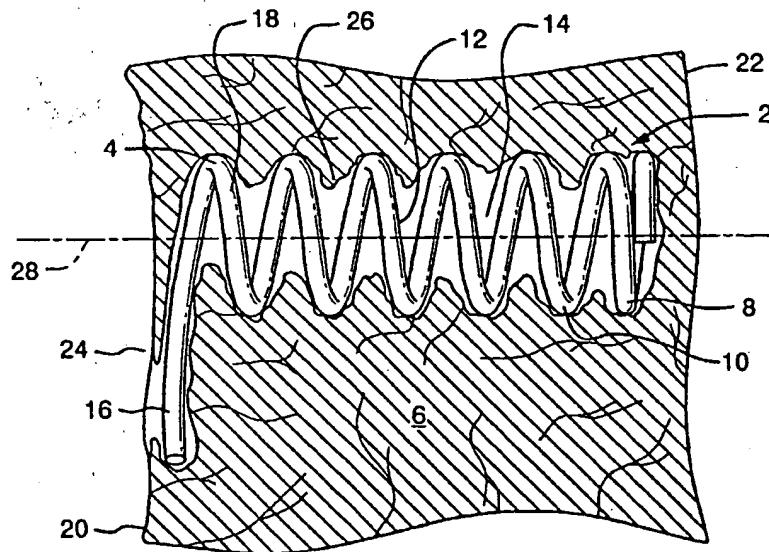
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61B 17/08		A1	(11) International Publication Number: WO 00/69345 (43) International Publication Date: 23 November 2000 (23.11.00)
(21) International Application Number: PCT/US00/13118 (22) International Filing Date: 12 May 2000 (12.05.00)		(81) Designated States: JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(30) Priority Data: 60/134,331 14 May 1999 (14.05.99) US 60/134,572 17 May 1999 (17.05.99) US		Published With <i>international search report</i> .	
(71) Applicant (for all designated States except US): C.R. BARD, INC. [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).			
(72) Inventors; and (75) Inventors/Applicants (for US only): WEISER, Michael, F. [US/US]; 515 Martins Pond Road, Groton, MA 01450 (US). GAMBALE, Richard, A. [US/US]; 382 Dunstable Road, Tyngsboro, MA 01879 (US). FORCUCCI, Stephen, J. [US/US]; 17 Pitcher Avenue, Medford, MA 02155 (US). FORDE, Sean [US/US]; 16 Frank Street, Watertown, MA 02472 (US). KWAN, Kellywan [US/US]; 45 Sunset Road, Dracut, MA 01826 (US).			
(74) Agent: PERULLO, John, F.; Kirkpatrick & Lockhart LLP, 75 State Street, Boston, MA 02109-1808 (US).			

(54) Title: IMPLANT ANCHOR SYSTEMS



(57) Abstract

The present invention provides anchoring mechanisms for tissue implants. The anchors (4) are integrated as part of the structure of the implant, and serve to resist migration of the implant from highly dynamic muscle tissue such as the myocardium of the heart. In implant devices configured as a flexible coil (8), various attributes of the coil may be altered to increase the anchoring capability of the device. The flexibility of the device may be increased to resist migration by changing the coil filament thickness, and pitch or filament material. Alternatively, the end coil may be altered to have a broader cross-sectional profile in engagement with the tissue or may include an anchoring barb. Additionally, methods of implanting a tissue implant device are provided.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Larvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Moritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NB	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

IMPLANT ANCHOR SYSTEMS

Field of the Invention

This invention relates to tissue implant devices and methods of their use. In 5 particular, the devices and methods concern systems for anchoring the implants in tissue so that they do not migrate after implantation.

Background of the Invention

There are a variety of applications for tissue implant devices in the human 10 body. Such applications include electrical pacing leads or other tissue monitoring devices or tissue support structures such as endoluminal stents. A device implanted in tissue may experience migratory forces applied by movement of the surrounding tissue into which the device has been implanted. Migration is especially a problem in muscle tissue that regularly contracts and relaxes around the device. Because the 15 device is static and is relatively inflexible, rather than absorbing the forces applied by the tissue, those forces act on the device to move it in the tissue. Migration of the device ultimately may lead to ejection of the device from the tissue. An ejected device could prove harmful to a patient if it enters the blood stream and blocks blood flow to a critical organ such as the brain.

20 Perhaps the most regular aggressive migratory forces created by muscle tissue may be experienced by implant devices which are placed in heart tissue. Because the heart muscle regularly contracts and relaxes in an exaggerated fashion to pump blood through the ventricle, implant devices located within that tissue have significant forces applied upon them. For example, the myocardial tissue comprising the exterior 25 wall of the heart at the left ventricle may increase in thickness by forty to sixty percent with each contraction. Conventional methods of anchoring a device to tissue such as by stapling or suturing prove difficult in applications where there is exaggerated and constant movement of the subject tissue because it is difficult to accurately apply a suture or staple to the intended location.

30 Implant devices for the heart have been disclosed in U.S. patent 5,429,144 (Wilk) and in U.S. patent 5,810,836 (Hussein et al.) for the purpose of restoring blood flow to the tissue of the heart. Conventional treatments of restoring blood flow to

heart tissue such as coronary artery bypass grafting have been supplanted in recent years by various methods of transmyocardial revascularization (TMR). TMR methods include creating channels into tissue of the heart either by needle acupuncture or coring with a hypodermic tube or by laser or mechanical ablative methods. Hussein

5 and Wilk attempt to maintain the patency of such channels by a placement of a mechanical implant device to the heart tissue to support an open pathway through which blood may flow. The Hussein patent discloses several stent embodiments that are delivered through the epicardium of the heart into the myocardium and positioned to be open to the left ventricle.

10 Due to the exaggerated migration forces experienced by an implant device in heart tissue as described above, it would be desirable to provide devices and methods for securely anchoring an implant in an associated dynamic region of tissue. It is a general object of the present invention to provide such an anchoring system for tissue implants, especially those intended for placement in the heart that may be 15 useful for revascularization of the heart tissue by various mechanisms.

Summary of the Invention

The present invention provides implant devices configured to become anchored within tissue so that they do not migrate despite experiencing aggressive 20 migration forces applied by the highly dynamic movement of muscle tissue that surrounds them. Additionally, methods for placing the devices so that they remain securely anchored within the tissue are provided. The devices are comprised of a flexible body, preferably formed from a helical wound spring.

The devices of the present invention not only exhibit improved anchoring 25 effectiveness, but also are configured to provide better durability and resistance to possible fracture in a highly dynamic tissue environment. The system for anchoring also controls injury to the tissue in which the device is implanted. Although tissue injury and its associated injury response may be a mechanism of initiating beneficial angiogenesis in tissue, it is preferable to have control over the amount of injury 30 created by implanting a device. The present anchoring systems provide the ability to reduce the trauma, tearing and injury to tissue that can be caused by anchoring a device to the tissue.

The devices of the present invention may be delivered to the intended tissue location percutaneously, through a catheter based system, transthoracically or surgically. Although the inventive devices and methods can be applied to implants intended for use in any region of the body, it is believed that the anchor systems are 5 especially useful as applied to implant devices for the heart configured to treat ischemia. Flexible implant devices may be configured to promote angiogenesis through a variety of mechanisms examples of which are described in detail in pending U.S. patent application serial nos. 09/164,173, 09/211,332 and 09/299,795.

Several embodiments of anchoring systems for flexible coil spring body implant 10 devices formed from a filament are disclosed. Generally, the spring implant devices may be considered to have a body having proximal and distal portions. In the present application, proximal is understood to mean the direction leading external to the patient and distal is understood to mean any direction leading internally to the patient. The implant devices discussed herein are delivered into the tissue in a distal direction 15 so that the body is implanted within the tissue and the proximal end of the device is approximately flush with the tissue surface or slightly submerged under the surface. In some embodiments the anchoring mechanism comprises an area of the device at its proximal portion or end having a profile that is larger than the profile of the distal portion of the device.

20 In a preferred embodiment, the anchoring tail at the distal portion of the device is configured to reside beneath the tissue surface after the device is implanted. The tail may comprise the proximal most coil of the device being flared outward to define an arm, perhaps curved, extending tangentially or spirally from the cylindrical profile of the implant device defined by the more distal coils of the device. The arm may be 25 bent distally to provide a projecting edge for engaging tissue. The device can be implanted in tissue over an appropriate delivery device discussed in detail below by applying an insertion force while rotating the device so that it "screws" into the tissue. The device is advanced until the most proximal coil becomes submerged slightly under the tissue. The configuration of the arm appears to resist migration of the 30 device either distally through the tissue or proximally back out of the tissue. Additionally, the arm appears to resist rotational movement of the device so that it

does not "unscrew" out of the tissue. A bulbous tip at the proximal end of the device aids in resisting rotational movement of the device.

In another preferred embodiment, the anchor system comprises an increasing taper of the overall diameter of the device in the proximal direction. Particularly, the 5 most proximal coils of the device increase in diameter size in the proximal direction to form a somewhat conical shape. The increasing taper may be present along the full length of the device or the most distal coils may be a constant diameter with the increasing taper in the proximal direction beginning at some point along the length of the device. As with the previous embodiment, the proximal portion of the device thus 10 defines a profile that is greater than the profile of the distal portion of the device. As with the previous embodiment, the most proximal coil of the tapered device is submerged below the surface of the tissue when the device is implanted.

The configuration of the above-described embodiments offer distinct advantages over other anchoring mechanisms. Both the arm and the tapered 15 embodiments do not require an abrupt transition in the filament shape to define a tail. An abrupt transition or bend in the filament may weaken the filament material causing it to break prematurely under the stresses created by dynamic loading of the surrounding tissue. Therefore, the absence of such a transition may be a distinct advantage and durability of the device. Additionally, because no more portion of the 20 device extends above to the surface of the tissue, no segment of the device will lie across a transition region which may develop between the highly dynamic muscle tissue into which the device is implanted and a more static tissue surface which may be created if fibrous tissue develops at the surface of the tissue where the device is implanted. Additionally, the submerged proximal portion of the device serves to resist 25 rotational movement of the device in the proximal direction.

In an alternate embodiment of the tissue implant device, a flexible coil spring body is configured to have a broadly wound proximal coil to serve as an anchoring tail. The broadly wound coil defines a larger profile than the more distal coils of the implant device. The broadly wound coil does not become submerged below the 30 tissue surface when the device is implanted, but rather, remains flush with the surface to resist migration of the device in the distal direction. The broadly wound coil may be a continuation of the helical coil winding that forms the body of the device or it may be

extended proximally from the body of the coil by a neck region. Because the broad wound coil has a profile that is larger than the body of the implant device, it tends to distribute migratory forces acting in the distal direction over a broader surface area of the tissue, preventing the tail from penetrating the tissue and allowing migration. The 5 broad wound coil that serves as a tail may be circular or a variety of non-circular shapes. It may be provided with or without barbs to lock into the tissue. The tail may be concentric with or off center from the longitudinal axis defined by the coils that make up the body of the implant device. Additionally, the proximal end of the coil may be secured to the broad loop by wrapping welding or by crimping a malleable sleeve 10 so that a closed loop configuration is maintained. The integrity of the proximal portion of the device that defines the tail may be enhanced by increasing the flexibility of the neck which joins the tail to the body with a coiled loop formed in the filament. Alternatively, the tail may be fortified by utilizing several coils abutting each other to 15 form the broad loop.

In an alternative embodiment of the invention, a flexible implant device formed from a helical spring body may be formed from a filament having a non-circular cross-section. For example, a filament having a rectangular cross-section may serve to prevent migration through the tissue in the axle direction by several mechanisms. When the helical coil is wound such that the major axis of the rectangular cross- 20 section is substantially perpendicular to the longitudinal axis of the body of the device greater axial flexibility is imparted to the spring, while maintaining sufficient radial stiffness to resist crushing by the tissue, then would be possible with a round cross-sectional filament material. Increased axial flexibility of the device permits it to move with surrounding tissue, absorbing forces that would otherwise tend to push the 25 device out of position in the tissue. Additionally, as surrounding tissue herniates through the individual coils of the device, the orientation of the major axis of the rectangular cross-section of the filament to be perpendicular to the longitudinal axis of the device presents a larger surface area engaging the tissue to resist axial migration. Alternatively, the major axis of the rectangular cross-section filament may be oriented 30 at an angle that is acute to the longitudinal axis of the device, so that the filament is canted in the proximal direction, to facilitate insertion of the device in the distal direction during implantation into the tissue. The canted orientation of the rectangular

cross-sectional filament still provides the flexibility benefits of the perpendicular orientation discussed above and may enhance anchoring capability by presenting a leading proximal facing edge that serves to grip into tissue.

In another aspect of the present invention, tissue implant devices are anchored

- 5 to the tissue with surgical adhesive. The surgical adhesive may be applied to the exterior device, similar to a coating prior to delivery, or may be applied to the device in tissue location after delivery. In the case of delivering adhesive after implantation, the delivery device may be configured to have a bore configured to deliver surgical adhesive to the interior device of the device after it has been implanted into tissue.
- 10 Alternatively, the surgical adhesive may be applied directly to the proximal end of the device at the tissue surface interface manually, after delivery of the device. Tissue implant devices having a wide variety of configurations may be anchored using a surgical adhesive such as that disclosed in U.S. patent no. 4,057,535. Such an adhesive is biocompatible and absorbable. Ultraviolet curing adhesives may also be
- 15 used, which form a structure after curing that is flexible and ultimately, absorbable.

In another aspect of the invention, the device is configured to resist migration in the tissue by exhibiting adequate flexibility in the axial direction to absorb migrational forces applied by surrounding tissue so that the device does not become displaced.

As mentioned above in connection with the non-circular cross-sectional filament

- 20 embodiment, the device can be configured to be adequately flexible in the axial direction while still providing sufficient radial stiffness to resist collapse of the device under force of the surrounding tissue. In the case of an implant device comprising a flexible helical spring body, variables such as filament diameter, spacing between individual coils and filament material may be altered to provide adequate axial
- 25 flexibility in a device to reduce migration. For example, a variety of filament materials may be used such as surgical grade stainless steels. Other materials may be used to vary the modulus of elasticity of the filament. Additionally, flexibility of the coil implant may be varied along the length of the coil, not only by varying spacing between coils and diameter of the filament along its length, but also by using two or more different
- 30 filament materials along the length of the filament that have different modulii of elasticity.

It is an object of the present invention to provide a tissue implant device that resists migration from the tissue into which it is implanted by offering improved anchoring capability.

It is another object of the present invention to provide a tissue implant device 5 having an anchor mechanism that controls the amount of injury inflicted upon tissue at the implant site.

It is yet another object of the present invention to provide an implant device that resists migration by its inherent flexibility and ability to absorb migratory forces exerted by surrounding tissue.

10 It is another object of the invention to provide an implant device that utilizes an anchoring mechanism that is submerged beneath the surface of the tissue into which the device is implanted.

It is another object of the present invention to provide a tissue implant device that utilizes an anchor mechanism that resides flush with the tissue surface when the 15 device is implanted.

It is yet another object of the invention to provide a method of implanting a tissue implant device so that it remains anchored in the tissue.

Brief Description of the Drawings

20 The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying diagrammatic drawings wherein:

FIG. 1 is a highly diagrammatic illustration of a tissue implant device of the present invention implanted in tissue;

25 FIG. 2 is an end view of the tissue implant device shown in FIG. 1;

FIG. 3 is an end view of a modified version of the tissue implant device shown in FIG. 1;

FIG. 4 is a side view of a modified version of the tissue implant device as shown in FIG. 1;

30 FIG. 5 is a highly diagrammatic illustration of a preferred embodiment of the tissue implant device of the present invention implanted in tissue;

- 8 -

FIG. 6 is an end view of a preferred embodiment of the tissue implant device shown in FIG. 5;

FIG. 7 is a side view of another preferred embodiment of the tissue implant device;

5 FIG. 8 is an isometric view of an alternate embodiment of the tissue implant device;

FIG. 9 is a isometric view of a variation of the alternate embodiment of the tissue implant device;

10 FIG. 10 is a isometric view of a variation of the alternate embodiment of the tissue implant device;

FIG. 11 is a isometric view of a variation of the alternate embodiment of the tissue implant device;

15 FIG. 12 is a isometric view of a variation of the alternate embodiment of the tissue implant device;

FIG. 13 is a side view of an alternate embodiment of the tissue implant device;

FIG. 14 is a partial sectional view of the tissue implant device shown in FIG.

13;

FIG. 15 is a partial sectional view of a variation of the tissue implant device shown in FIG. 13;

20 FIG. 16A is a side view of a tissue implant device delivery system;

FIG. 16B is a detailed side view of the distal end of the tissue implant device delivery system; and

FIG. 16C is a detailed side view of the distal end of the tissue implant device delivery system carrying an implant.

25

Description of the Illustrative Embodiments

FIG 1 shows a partial sectional side view of a preferred embodiment of an implant device configured for improved anchoring. The implant device 4 comprises a helical spring body 8 formed of a plurality of individual coils 10. The helical spring body 8 defines an interior 12 which maintains an open cavity 14 within the tissue 6 when the device is implanted. The anchor mechanism comprises a laterally extending arm, which extends from the most proximal coil 18 of the spring body 8 to

define a lateral extent away from the longitudinal axis 28 of the device that is greater than the overall diameter of the coil body 8.

The implant device is particularly useful in treating ischemic tissue such as that often occurs in a myocardium of the heart. As shown in FIG. 1 the implant device

5 may be inserted into the myocardium 6 through the epicardial surface 20 at entry site 24 such that the device extends the majority of the thickness of the myocardium towards endocardial surface 22. Also, the device is fully implanted within the tissue such that the proximal laterally extending arm 16 is submerged within the tissue.

FIG. 2 shows an end view of the device 2 and in particular the laterally 10 extending arm 16, which is configured to prevent migration of the device. As is seen in FIG. 2 the arm extends from the most distal coil 18 in an tangential direction from the round coil. The arm 16 then curves slightly in the direction of the curvature of the coil. Preferably the lateral extent of the arm beyond the outside diameter of the device is approximately 1 - 3 mm. Generally the diameter of the body 8 of the coil is 15 preferably on the order of 2 - 3 mm. The arm serves to provide increased surface area engaged with the tissue to prevent migration in an axial direction through the tissue. Furthermore, the implantation of the arm into the tissue causes it to prevent rotation of the device so that the device cannot back out of its tissue implant site.

FIG. 3 shows a variation of the laterally extending arm 16 having a bend 30 20 and second lateral extent 32. The alternate embodiment of the laterally extending arm 16 shown in FIG. 3 provides additional surface area and may serve additionally help to prevent rotation of the device. Variations of the shape of the laterally extending arm are possible and are considered within the scope of the invention.

Another alternative design of the lateral extending arm is shown in FIG. 4. The 25 lateral extending arm 16 is shown to have a distally projecting bend 34 at the proximal end 36 of the arm. The distally projecting bend 34 may serve to further resist axial movement in the distal direction when the device is implanted in tissue because it serves more as a barb to claw into the tissue to resist movement. The penetration of the bend also serves to resist rotation of the device. Alternatively, the bend 34 need 30 not be as extreme as shown in FIG. 4, but rather the bend may be subtle, only to the extent that the arm 16 extends horizontally rather than following the acute angle of the helical pattern of the most distal coil 18.

- 10 -

FIG. 5 shows another preferred embodiment of the implant device. A semi-tapered coil spring 40 may also provide adequate anchoring in dynamic tissue such as the tissue of the myocardium while meeting the objectives of the invention. The implant 40 comprises a helical coil spring 42 having a proximal portion 44 and a distal portion 46. The individual coils 48 of the spring 42 increase in diameter through the proximal portion 44. Each coil increases in size in the proximal direction. However, the coils of the distal portion 46 are a constant diameter that is somewhat smaller than the diameter of the coils of the proximal portion. The most proximal coil 50 does not extend laterally outward as with the previous embodiment, rather it terminates in its position as part of the helical coil arrangement. The proximal end of the coil may be formed to have a bulbous shape to further resist penetration of the tissue after the device has been implanted. As with the previous embodiment, the tissue tends to herniate at points 26 along the length of the implant. In experiments, the device 40 has shown to resist migration and rotation by virtue of the partial increase in taper at the proximal portion 44 of the device. This configuration may also serve to resist migration due to the enhanced flexibility of the proximal coils by virtue of their increased diameter. Increasing the overall diameter of the proximal coils (while maintaining the same filament thickness) serves to increase the flexibility of those coils.

FIG. 6 shows an end view of the implant device 40 having a partial taper at the proximal portion 44. As with the first embodiment, the most proximal coil 50 is submerged within the tissue 6 when the device is implanted. The submersion of the most proximal coil provides the advantages detailed above and additionally avoids placing a section of the coil across the transition between the tissue and tissue surface, which may tend to move differently placing an increased stress on the device and possibly leading to premature failure. FIG. 7 shows a variation of the preferred embodiments discussed above wherein the increasing taper is present throughout the length of the device such that each coil increases in diameter in a direction from the distal end 80 to the proximal end 84. The full taper embodiment 80 is believed to offer the same benefits as described in connection with the device shown in FIG. 5. In the above described tapered embodiments the smaller distal coils 46 may define a diameter on the order of approximately 2.2 millimeters measured to the outside diameter of the coils and the larger diameter, maximum extent of the taper may be on

the order of 4.5 to 5 millimeters. The devices are preferably on the order of 7 - 8 mm in length.

FIG. 8 shows an alternate embodiment of an implant device having an anchoring mechanism. The coil device has an interior 98, which is defined by the 5 individual turns 120 of the coil. The helical coil 96 defines a frame, which holds back surrounding tissue so that blood may pool in the interior chamber, coagulate and become fibrin. Spaces 122 between individual turns of the coil permit communication between the interior chamber 98, where fibrin will grow and the blood and tissue that surround the device. Open ends 124 also permit communication between the interior 10 chamber 98 and surrounding tissue. The coil 96 has a tail 128 configured to resist excessive penetration of the device into the subject tissue so that the overall depth that the device is implanted in the tissue is controlled. The tail 28 may be configured in a variety of forms. The example of a tail shown in FIG. 8 comprises a single broad coil joined to the main body 125 of the device by an extension 127, which may be a 15 continuation of the most proximal coil 116. When the device is implanted in tissue, the broad coil of the tail is positioned to be flush with the surface of the tissue. The broad coil tail distributes the migratory forces experienced by the device over a broad area of tissue surface. The tail resists penetration of tissue surface thereby preventing migration of the device further into the tissue. Additionally, filament 126 20 from which the coil is formed may be a solid material or may, itself, be a coil spring structure having a plurality of openings between turns of the coil, which serve to permit herniation of surrounding tissue into the coil for anchoring capability. The broad coil 120 defining tail 128 has a proximal end 130 which is preferably joined to the broad coil to maintain the coil circular shape. The proximal end 130 can be joined 25 to the broad coil 128 by a variety of means such as welding as is shown by weld 132.

FIG. 9 shows an alternative embodiment of joining the proximal end 130 to the broad coil 128. The alternative embodiment comprises wrapping the portion of the filament adjacent the proximal end 130 around the broad coil 128 in several turns 134. FIG. 10 shows another alternative embodiment useful for joining the proximal 30 end 130 of the coil 96 to the broad coil 128. The alternative embodiment utilizes a malleable sleeve 136 to encompass both a portion of the broad coil 128 and the distal end of the coil 130. The malleable sleeve is then crimped to mechanically grasp the

distal end 130 and broad coil and join them so that the circular shape of the broad coil 128 is maintained.

The broad coil 128 need not be a circular shape but may have a variety of broad shapes capable of serving to disperse migratory forces over a broad surface area of tissue when the device is implanted. FIG. 11 shows a possible non-circular shape for the broad coil comprising a star shaped 137. FIG. 12 shows yet another alternative embodiment for the shape of the broad coil 128. In FIG. 12 a somewhat oval broad coil 138 is shown. Additionally, the broad coil 138 has plurality of distally projecting protrusions 139, which may increase the grasp of the coil into the tissue to prevent migration.

FIG. 13 shows yet another alternate embodiment of a tubular frame device. The canted coil device 140 is formed from a filament 142 of rectangular cross-section such as a strand of flat wire. As shown in FIG. 14, the coil is formed so that the major cross-sectional axis 147 of the rectangular wire is oriented at an acute angle to the longitudinal axis 150 of the coil 140. The orientation gives each turn 146 of the coil a projecting edge 144, which tends to claw into tissue to serve as an anchoring mechanism for the device.

FIG. 15 shows a wrapped ribbon implant embodiment. The implant 90 is formed by a filament of a rectangular cross-sectional filament around a ribbed mandrel. In the present embodiment, the major axis 147 of the rectangular cross-section ribbon is oriented substantially perpendicular to the longitudinal axis 150 of the implant, as is shown in FIG. 15. In this configuration, the major axis 147 of the coils 142 of the rectangular ribbon do not extend radically from the longitudinal axis 150 of the implant 140 at an acute angle. With greater coil surface area extending away from the longitudinal axis of the implant, the implant is believed to be more stable and less likely to migrate once implanted within the myocardium. The implant is preferably formed from 316 stainless steel rectangular cross-section forming wire. Preferred dimensions for the rectangular cross-section filament are on the order of .003 inches to .005 inches for the minor axis width and .015 to .018 inches for the major axis.

Each of the implant devices of the present invention may be delivered to their intended tissue location surgically. FIGS. 16A - 16C show an example of a surgical

delivery device that may be used to deliver the implants into tissue such as that of the myocardium of the heart. The delivery device, shown in FIG. 16A, comprises an obturator 180 that includes a main shaft 182, by which it can be gripped and manipulated. The distal end 181 of the shaft 182 is shown in detail in FIG 16B and includes a reduced diameter device support section 184 having a sharp distal tip 186 adapted to pierce tissue. The diameter of the shaft segment 184 is such as to fit closely within the interior of the devices. The proximal end of the segment 184 terminates in a shoulder 188 formed at the junction of a proximally adjacent, slightly enlarged diameter portion 190 of the shaft. The distal end of the device support segment 184 may include a radially projecting pin 192 dimensioned to project and fit between adjacent turns of the coils of a device. The pin 192 engages the coils in a thread-like fashion so that after the assembly has been inserted into the tissue, the obturator 180 can be removed simply by unscrewing the obturator to free it from the implanted coil. Alternatively, the obturator may be configured without the projecting pin 192 so that the device can be slipped on and off the obturator, without screwing. When an implant device 2 is mounted on the obturator 180, as is shown in FIG. 16C the proximal end of the device may bear against the shoulder 188, and the tail 28, if so equipped may extend along the segment 190 of the obturator.

In use, the intended tissue location is first accessed surgically, such as by a cut-down method. The obturator, with an implant device loaded on to segment 184, then may be advanced into the tissue to deliver the implant. The sharp tip pierces the tissue permitting the obturator and implant to be pushed inward into the tissue. In the example of delivery to the myocardium, the epicardial surface of the heart is accessed and penetrated by the obturator to deliver the implant. The shoulder 188 prevents proximal movement of the implant along segment 184 during delivery. Preferably, the distal end of the obturator is projected to, and slightly beyond, the endocardium to place the implant device. The obturator then may be unscrewed and separated from the implant device. If the obturator is configured without the pin 192, the obturator may be withdrawn directly from the device and the tissue. Simply applying light closure pressure to the epicardial puncture will cause the puncture hole to clot at the epicardium.

- 14 -

An alternative method of anchoring the device comprises applying a surgical adhesive to the site of the implant such that adhesive is joined to the implant device and to surrounding tissue so that it is adhered. As described previously, one method of applying the surgical adhesive may comprise applying it directly at the surgical site

5 or manually or delivering a quantity of surgical adhesive through the obturator delivery device directly to the cavity 18 created in the tissue by the device.

In yet another method of providing a device that resists migration, each of the above described implant embodiments may exhibit improved resistance to migration by being configured to have enhanced axial flexibility. The flexibility may be

10 controlled by a number of factors. One factor in controlling the flexibility of a helical coil device is to decrease the spacing between adjacent coils. Wire diameter may vary between .006 inches to .010 inches for the above described devices with .007 to .008 being preferred. Preferred pitch with such diameters may be on the order of .25mm - 1mm. The flexibility of the spring implant may also be increased by

15 increasing the overall diameter of the coils.

Generally, surgical grade stainless steels are used to fabricate the implant devices discussed above, but other materials having different modulii of elasticity such as nickel titanium alloys can be used. Additionally, implants formed from 2 or more different materials can be formed to provide varying flexibility. Different material

20 filaments can be joined by welding or crimping of a malleable sleeve.

From the foregoing it will be appreciated that the invention provides a novel approach to providing an anchoring system for implant devices. The devices and methods of the present invention are simple and easy to apply to a wide range of implant designs.

25 It should be understood however, that the foregoing description of the invention is intended merely to be illustrative thereof and that other modifications, embodiments and equivalents may be apparent to those who are skilled in the art without departing from its spirit. Having thus described the invention what we desire to claim and secure by letters patent is:

CLAIMS

1. A tissue implant device configured to resist migration in the tissue.
- 5 2. A tissue implant device as defined in claim 1 further comprising a flexible body having proximal and distal portions each defining a profile, the proximal end having a larger profile than the proximal end.
- 10 3. A tissue implant device as defined in claim 2 wherein the flexible body defines an exterior, a hollow interior, and at least one opening between the interior and exterior.
- 15 4. A tissue implant device as defined in claim 3 further comprising: a tail at the proximal portion.
5. A tissue implant device as defined in claim 4 wherein the tail defines a profile that is larger than the distal portion of the body.
- 20 6. A tissue implant device as defined in claim 5 wherein the tail is configured to remain at the tissue surface when the device is implanted.
7. A tissue implant device as defined in claim 5 wherein the tail is configured to be implanted in the tissue when the body of the device is implanted.
- 25 8. A tissue implant device as defined in claim 2 wherein the flexible body comprises a helical spring.
9. A tissue implant device as defined in claim 1 wherein the device is configured to resist migration by exhibiting adequate longitudinal flexibility to 30 substantially absorb migratory forces placed on it by the surrounding tissue.

- 16 -

10. A tissue implant device as defined in claim 9 wherein the flexible body comprises a helical spring.
11. A tissue implant device as defined in claim 1 further comprising a surgical adhesive associated with the device.
5
12. A tissue implant device as defined in claim 11 wherein the surgical adhesive is associated with the device after the device is implanted in tissue.
- 10 13. A tissue implant device as defined in claim 8 wherein the helical spring has varying flexibility along its length.
14. A tissue implant device as defined in claim 8 wherein the helical spring is formed from a filament having varying modulus of elasticity.
15
15. A tissue implant device as defined in claim 13 wherein the filament is comprised of a plurality of materials of varying modulii of elasticity.
16. A tissue implant device as defined in claim 13 wherein the varying flexibility is created by varying the distance between individual coils of the helical spring.
20
17. The tissue implant device as defined in claim 13 wherein the helical spring is formed from a filament having a varying thickness along its length, which creates varying flexibility along the length of the helical spring.
25
18. A tissue implant device as defined in claim 7 wherein the flexible body comprises and helical spring and the tail is formed by a more broadly wrapped coil adjacent to the proximal portion of the body forming an arm that extends laterally from the longitudinal axis of the device in the diameter of coils that comprise the body of the spring.
30

19. A tissue implant device as defined in claim 18 wherein the flexible body comprises a helical spring the tail is deformed to be out of plane with the helical orientation of coils comprising the body of the spring.

5 20. A device as defined in claim 8 wherein individual coils of the helical spring have a constantly increasing diameter from the proximal portion to the distal portion.

10 21. A tissue implant device as defined in claim 8 wherein coils of the distal portion define a constant diameter and coils of the proximal portion define an increasing diameter in the proximal direction.

15 22. A tissue implant device as defined in claim 6 wherein the flexible body comprises a helical spring and the tail comprises a broadly wound most proximal coil of the spring having a diameter that is greater than the diameter of coils of the body of the device.

20 23. A tissue implant device as defined in claim 22 wherein the broadly wound coil is concentric with the body of the device.

24. A tissue implant device as defined in claim 22 wherein the broadly wound coil has a center which is offset from the longitudinal axis of the body of the device.

25 25. A tissue implant device as defined in claim 22 wherein the tail includes a proximal end of the spring and the proximal end is secured to the broadly wound coil.

26. A tissue implant device as defined in claim 25 wherein the proximal end is joined to the broad loop by being wrapped around the loop.

- 18 -

27. A tissue implant device as defined in claim 26 wherein the proximal end of the coil extends distally from the broad loop coil after it has been wrapped about the broad loop coil to serve as a barb.

5 28. A tissue implant device as defined in claim 25 wherein the proximal end is joined to the broad loop coil by welding.

10 29. A tissue implant device as defined in claim 25 wherein the proximal end of the coil is joined to the broad loop coil by a malleable sleeve crimped around the proximal end and broadly wound coil to secure the proximal end to the coil.

15 30. A tissue implant device as defined in claim 22 wherein the broadly wound core is non-circular.

20 31. A tissue implant device as defined in claim 25 wherein the broadly wound coil is joined to the body of the device by a neck portion.

32. A tissue implant device as defined in claim 31 wherein the neck comprises at least one straight segment.

25 33. A tissue implant device as defined in claim 31 wherein the neck comprises a coil lying in a plane that is substantially parallel to the longitudinal axis of the device.

34. A tissue implant device as defined in claim 8 wherein the helical spring is formed from a filament having a non-circular cross-sectional shape.

35. A tissue implant device as defined in claim 34 wherein the cross-sectional shape of the filament is rectangular.

36. A tissue implant device as defined in claim 35 wherein the major axis of the rectangular cross-section is substantially perpendicular to the longitudinal axis of the device.

5 37. A tissue implant device as defined in claim 35 wherein the major axis of the rectangular cross-section is at an acute angle to the longitudinal axis of the device.

10 38. A method of implanting a tissue implant device comprising:
providing an implant device having a flexible body with proximal and distal ends and an anchoring tail at the proximal end;
providing a sharp tip delivery device configured to penetrate tissue and releasably retain the tissue implant device;
associating the implant device with the implant delivery device;
15 accessing the desired tissue implant site;
applying a penetrating force to the implant and implant delivery device combination such that the combination penetrates tissue to a clinically effective penetration depth to implant the device;
withdrawing the implant delivery device from the implanted implant
20 device.

25 39. A method as defined in claim 38 wherein the implant device and delivery device combination is rotated while penetrating forces are applied to screw the device into the tissue.

40. A method as defined in claim 39 wherein the tail of the implant device is submerged below the surface of the tissue after implantation.

30 41. A method as defined in claim 39 wherein the tail of the implant device remains exposed at the surface of the tissue after implantation.

- 20 -

42. A method of implanting a tissue implant device to promote angiogenesis within a tissue comprising:

providing a tissue implant device configured to be anchored within tissue so that it does not migrate from the tissue after implantation.

5

43. A method of implanting a tissue implant device as defined in claim 42 wherein the device is delivered percutaneously.

44. A method of implanting a tissue implant device as defined in claim 42
10 wherein the device is delivered transthoracically to the intended tissue location.

45. A method of delivering a tissue implant device as defined in claim 42
wherein the device is delivered surgically to the intended tissue location.

15 46. A method of anchoring a tissue implant device within tissue comprising:
providing an implantable body;
providing a delivery device configured to carry the implantable body to
an intended tissue location and implanting the device in tissue;

20 associating the body with the delivery device and implanting the body in
tissue at the intended location;

applying a surgical adhesive at the site of the implant to secure the body
to the tissue.

47. A method of implanting an implant device as defined in claim 46 wherein
25 the surgical adhesive is applied to the implant site by the delivery device after
implantation.

48. A method of delivering an implant device as defined in claim 46 wherein
the surgical adhesive is applied to the body prior to implantation.

30

49. A method of implanting an implant device configured to resist migration
in tissue comprising:

- 21 -

providing a flexible spring body implant device having sufficient longitudinal flexibility to absorb migratory forces applied on the device by surrounding tissue after implantation;

inserting the flexible spring body into tissue.

1/7

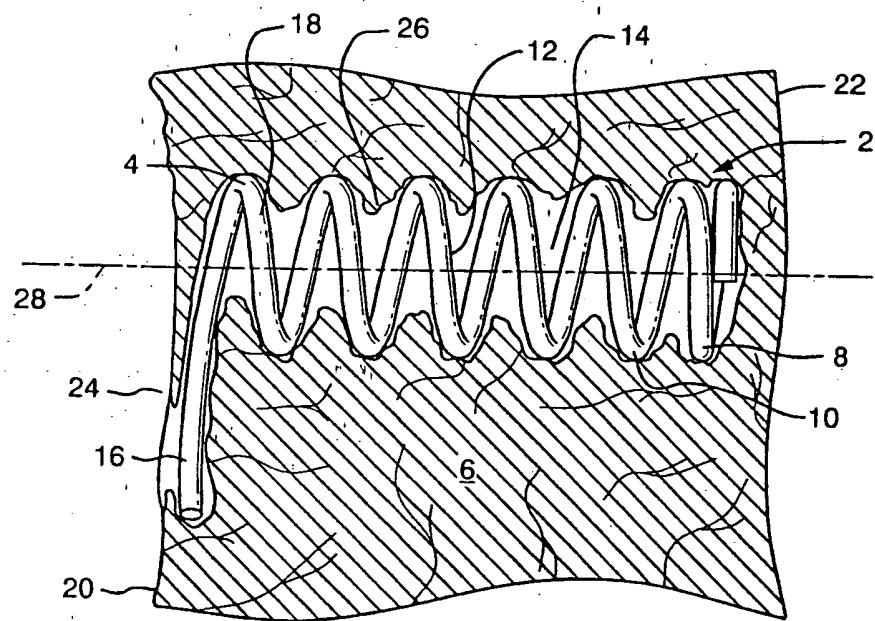


FIG. 1

2/7

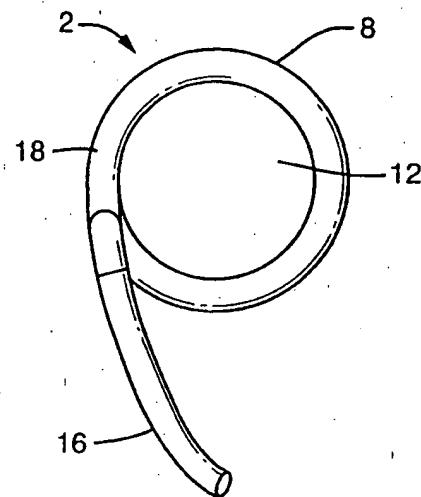


FIG. 2

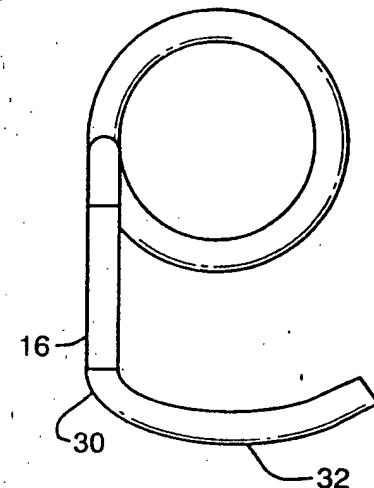


FIG. 3

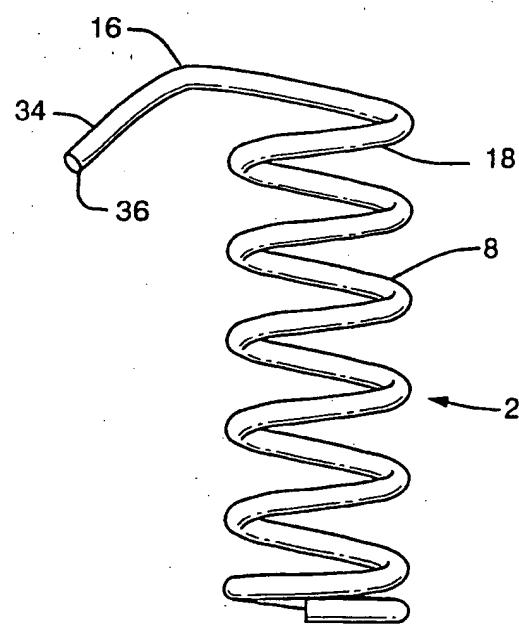


FIG. 4

3/7

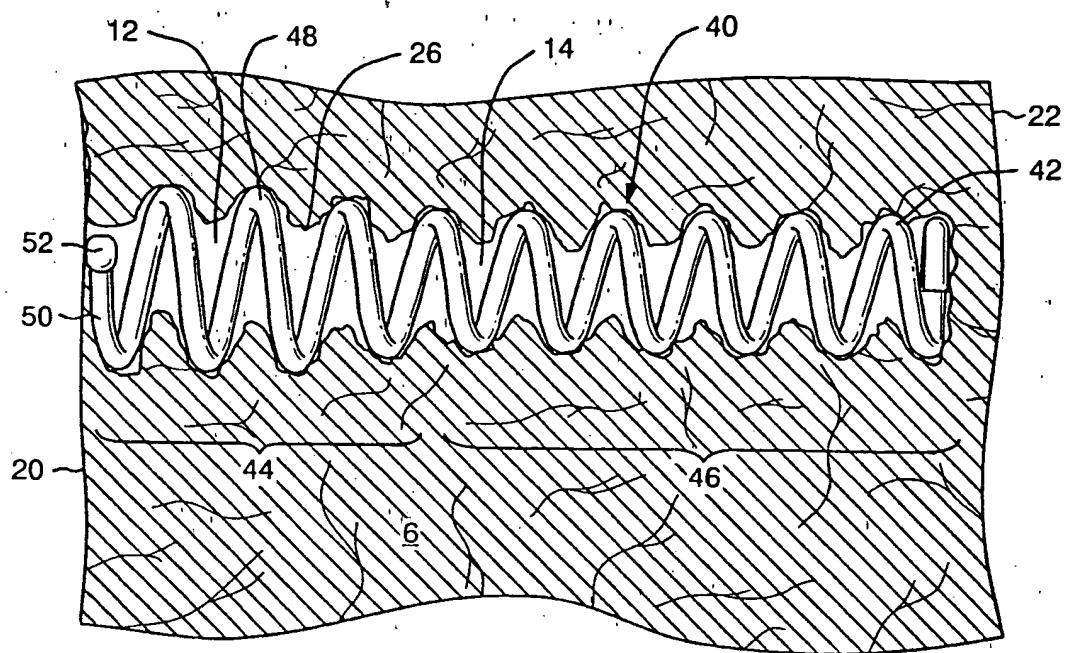


FIG. 5

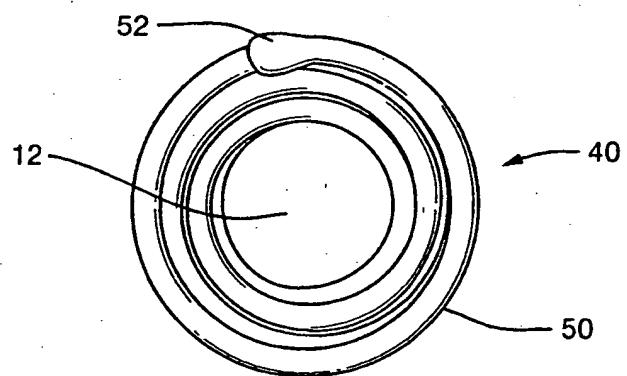


FIG. 6

4/7

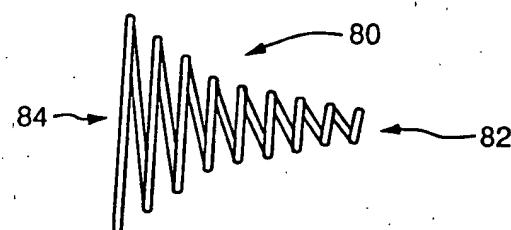


FIG. 7

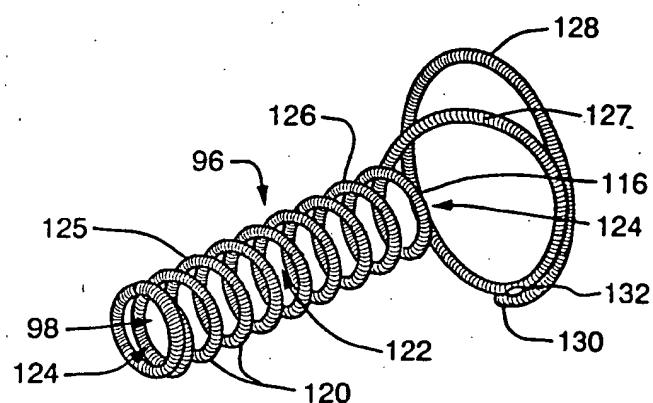


FIG. 8

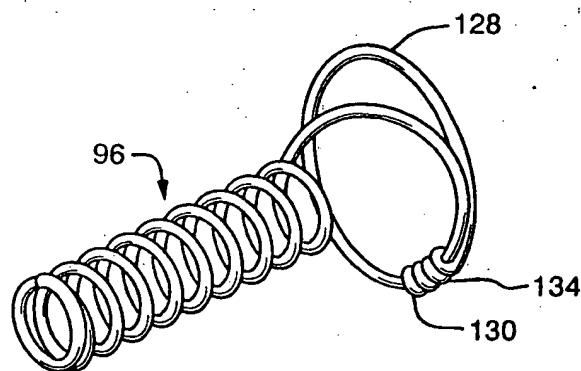


FIG. 9

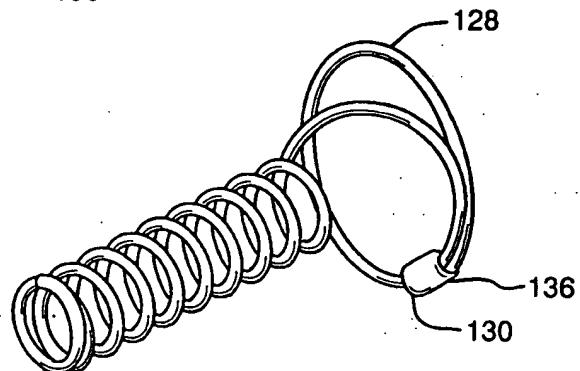


FIG. 10

5/7

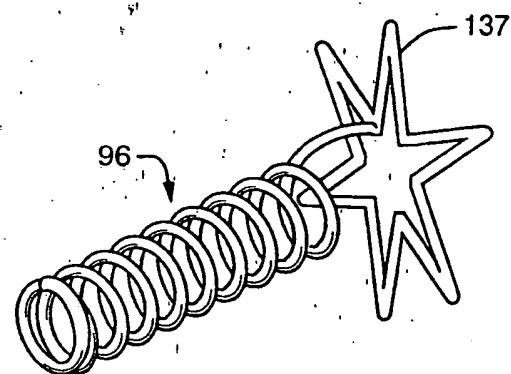


FIG. 11

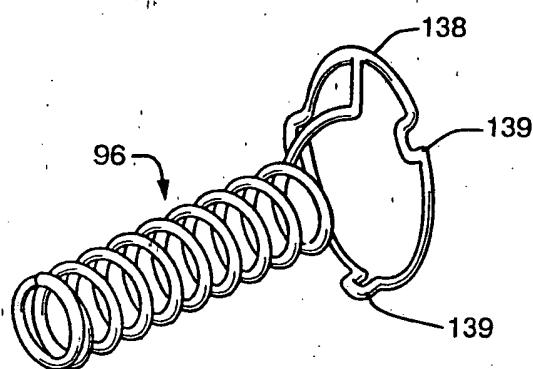


FIG. 12

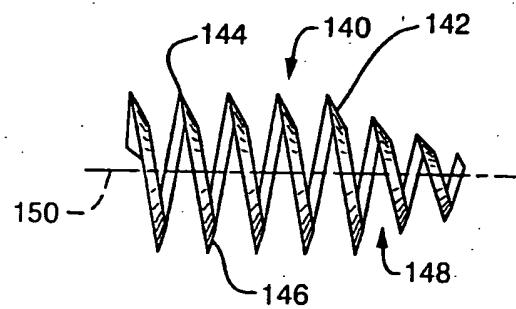
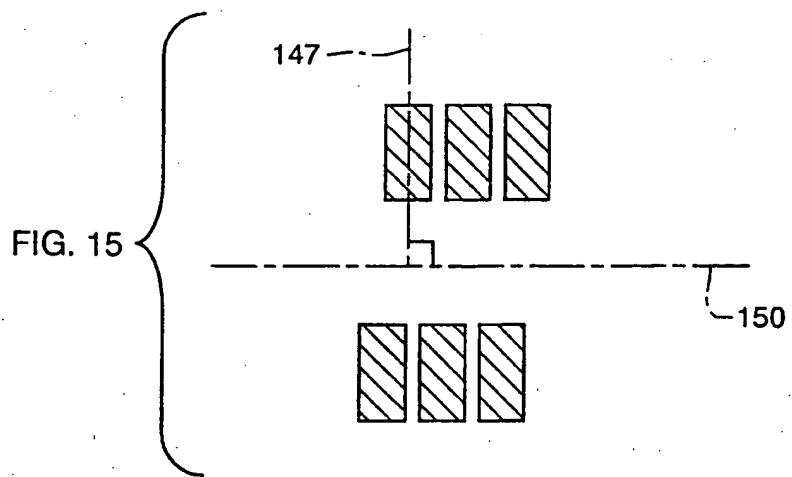
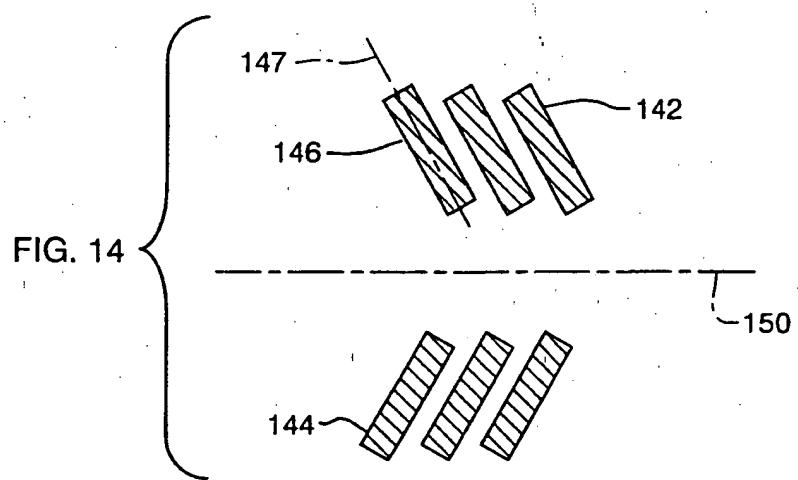


FIG. 13

6/7



7/7

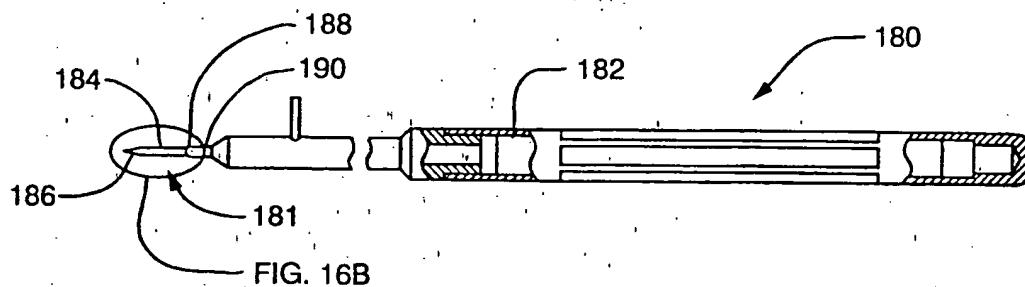


FIG. 16A

188

190

182

180

184

186

FIG. 16B

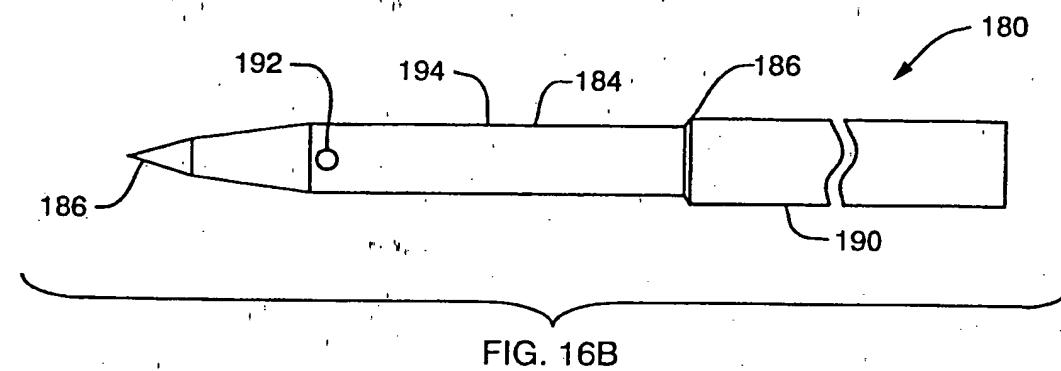


FIG. 16B

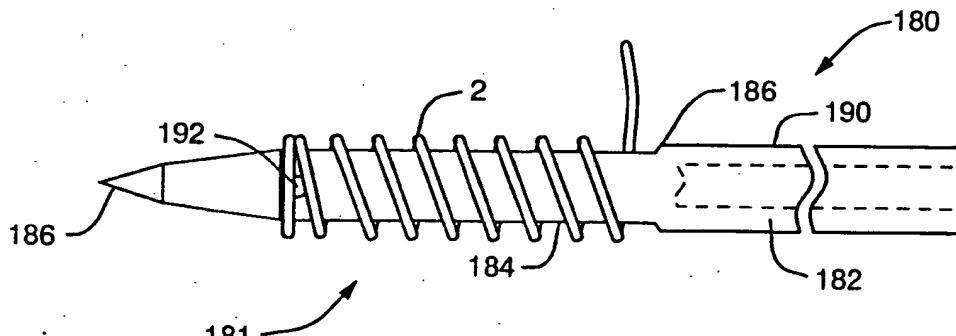


FIG. 16C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/13118

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/08

US CL :606/213

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/108, 185, 191, 200, 213; 607/116

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No..
X	US 4,904,264 A (SCHEUNEMANN) 27 February 1990, Fig. 7, and col.7 lines 10-15.	1-16, 18-49
X,P	US 6,053,924 A (HUSSEIN) 25 April 2000, Figs. 1, 4, 5, and 7.	1-11, 13-46, 49
X	US 5,366,493 A (SCHEINER et al.) 22 November 1994, Fig.1.	1-49
Y		
X,P	US 5,980,514 A (KUPIECKI et al.) 09 November 1999, Figs. 2 and 4.	1-49
Y,P		

Further documents are listed in the continuation of Box C.

See patent family annex.

Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

04 AUGUST 2000

Date of mailing of the international search report

24 AUG 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

LIEN NGO

Telephone No. (703) 305-0294

THIS PAGE BLANK (USPTO)